REMARKS

I. Status of Claims

Claims 1-25 are pending. Claims 1, 8 and 15 are independent.

A) Claims 1-7 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,867,821 to Ballantyne et al (hereinafter "Ballantyne") in view of U.S. Patent No. 6,283,761 to Joao (hereinafter "Joao"), and further in view of U.S. Patent No. 5,937,387, to Summerell et al (hereinafter "Summerell").

B) Claims 8-14 are rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al and Joao in view of U.S. Patent No. 5,557,514, to Seare et al (hereinafter "Seare").

C) Claims 15-21 and 23-25 are rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al and Joao in view of U.S. Patent No. 5,319,355 to Russek (hereinafter "Russek") and further in view of U.S. Published Application No. 2003/0055679, to Soll et al (hereinafter "Soll").

D) Claim 22 is rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne, Joao, Russek, Soll et al in view of Official Notice.

II. Rejections Under 35 U.S.C. § 103(a)

The independent claims 1, 8 and 15 recite storing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes in a database of a computer network, and patient health-related data pertaining to respective patients. Further, each of these claims has been amended to more clearly recite that the accumulated health-related data is revised or updated based on the patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions. Thus, recitation of these two different types of data makes it clear that simply updating the patient health-related data is not the same as updating or revising accumulated health-related data that reveals population

trends and identifying improvements in standards of care and medical practices. As discussed below, the Applicants submit that none of the applied references discloses or suggests singly, or in combination, a system that aggregates data revealing population trends and outcomes, and modifies the accumulated health-related data based on patient health-related data for identification of improvements in medical practices.

A. Rejection of Claims 1-7

Claims 1-7 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,867,821 to Ballantyne et al (hereinafter "Ballantyne") in view of U.S. Patent No. 6,283,761 to Joao (hereinafter "Joao"), and further in view of U.S. Patent No. 5,937,387, to Summerell et al (hereinafter "Summerell").

In the Office Action, Ballantyne is relied on to purportedly teach:

> *"a computer network comprising a database containing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes and at least one data access device configured to provide a health care provider access to said computer network and said database, said computer network configured to receive said patient health-related data pertaining to respective patients from said remote monitoring stations[[,]] and provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data, and said computer network being configured to revise said accumulated health-related data based on said patient health-related data for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions,"* as recited in claim 1.

The referenced sections of Ballantyne and the remainder of Ballantyne, however, merely refer to the storage of patient medical health records and not to accumulated data relating to population trends and outcomes, nor revision of this data to identify improvements of standards of care and medical practices.

On pages 24-25 of the "Response to Arguments" section of the final Office Action, the Examiner states "that a broad, yet reasonable interpretation of

Applicant's claim language reads on the teachings of Ballantyne...That is, patient medical records (i.e., health-related data pertaining to conditions and treatment) do reveal various information, including, but not limited to, population trends and outcomes." Applicants respectfully disagree.

Claim 1 recites, among other limitations, (1) remote monitoring stations that receive "patient health-related data pertaining to a respective patient;" (2) a database in a computer network containing "accumulated health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes;" and (3) the computer network being "configured to *revise said accumulated health-related data based on said patient health-related data* for identification of improvements in standards of care and medical practices that can be made for different ones of the health-related conditions."

The patient's electronic medical record described in Ballantyne contains only patient-specific information and not health-related data pertaining to health-related conditions and treatments that reveals population trends and outcomes as claimed. See, for example, col. 15, line 40 through col. 16, line 13 of Ballantyne. The storage of plural patient electronic medical records at the master library of Ballantyne and the regional medical library of Ballantyne also do not teach or suggest the inventions recited in claims 1, 8 and 15. The storing of different patient electronic medical records in the master library, and the acquiring of information on specific medical research fields by the regional library, described in Ballantyne do not teach revising the acquired information based on the patient medical records. By contrast, claims 1, 8 and 15 recite revising or updating said accumulated health-related data based on said patient health-related data received at the computer network from a remote monitoring station or healthcare manager.

The Office Action admits that Ballantyne fails to disclose:

(1) "*said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said*

treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools"; and

(2) *"said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient."*

The Office Action relies on (1) Summerell and (2) Joao, respectively, to purportedly teach these claim limitations. On page 25 of the "Response to Arguments" section of the final Office Action, the Examiner states that he disagrees with Applicants' earlier contention that Summerell does not disclose an electronic self-management tool that allows a patient to integrate a health care provider's established treatment program, but rather seeks to provide a tool for users to select their own wellness plan without involvement of a heath care provider. The Examiner cites Fig. 2 and column 4, lines 15-19 and states that these citations can be broadly construed to read on "health care provider." Applicants respectfully disagree. Fig. 2 is an introductory page for a user who is a patient and not a heath care provider. As stated on column 8, lines 53-65 of Summerell, the patient is guided to enter personal information. As stated in column 5, lines 47-53 and lines 60-62 of Summerell, the wellness measurement and wellness options systems disclosed therein seek to reduce the difficult and time-consuming data collection task of physicians by providing systems that "collect data directly from the patient." Thus, the Examiner's broad interpretation of Summerell is in contradistinction to what the references actually teaches. The reliance on column 4, lines 15-19 of Summerell in support of the Examiner's position is also a misinterpretation. The questions to be asked of a doctor mentioned column 4, lines 15-19 of Summerell refer to questions to ask as a patient "progresses in the personalized wellness program" that is set up as a result of the patient using the system, that is, *after* the system is used by the patient to set up and obtain his/her wellness program. Thus, the health care provider is not involved in the set up of the program as the Examiner suggests. The physician can merely augment the data entered by the patient

into the system with test results (e.g., patient's blood pressure). See column 5, lines 60-67 of Summerell.

In view of the foregoing, the 35 U.S.C. § 103(a) rejection of claim 1 and its dependent claims 2-7 is respectfully requested.

B. Claims 8-14

Claims 8-14 are rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne and Joao in view of U.S. Patent No. 5,557,514, to Seare et al (hereinafter "Seare").

For similar reasons stated above in connection with claim 1, neither Ballantyne nor Summerell single or in combination teaches the following recitations of method claim 8 which are similar to apparatus claim 1:

> "*storing accumulated health-related data pertaining to health-related conditions and treatment that reveals population trends and outcomes in a database of a computer network;*
>
> *receiving at said computer network said patient health-related data from said remote monitoring stations pertaining to respective patients;*
>
> *controlling said computer network to provide a health care provider with electronic treatment establishment tools to establish treatment programs for said patients based on their respective patient health-related data and said accumulated health-related data;*
>
> *controlling said computer network to revise said accumulated health-related data based on said patient health-related data*," among other limitations.

Seare and Joao do not overcome these deficiencies. Even if Seare or Joao could arguably be reasonably interpreted to disclose said accumulated health-related data that reveals population trends and outcomes as claimed, Applicants respectfully submit that there is nothing in either of these two references that discloses or suggests revising said accumulated health-related data based on said patient health-related data from remote monitoring stations, or determining from said aggregated data recommendations for improving treatment programs. As stated above, Joao discloses using the disclosed system 10 to determine if a diagnosis and/or treatment is "in-line" with *current standards* for the given

healthcare field (see column 28, lines 38-48), but is silent regarding storing accumulated data revealing population trends and outcomes, and revising said accumulated based on patient health-related data, and determining recommendations for improving treatment programs, as recited in claim 8. The response described in column 38, lines 55-56 of Joao can include an evaluation of a diagnosis and/or prescribed treatment that is apart from the patient's response to the prescribed treatment, and therefore does not suggest determining improvements from outcomes as claimed but rather only determines if the diagnosis and/or treatment is "in-line" with *current standards* for the given healthcare field described earlier in Joao at column 28, lines 38-48.

In the Office Action, Seare et al is relied on to purportedly teach the following claim recitations:

> *"receiving economic data relating to protocols used in said treatment programs;*
>
> *aggregating said patient health-related data, said clinical data and said economic data with said accumulated health-related data comprising population outcomes and generic standards of care; and*
>
> *determining from said aggregated data recommendations for improving the treatment programs."*

Seare et al teaches "converting raw medical providers billing data into an informative historical database" (see column 4, lines 34-36) to provide a mechanism for assessing medical services utilization patterns of medical providers and thereby generating statistically-generated medical provider utilization profiles.

Applicants respectfully submit, for reasons stated above, that Ballantyne does not disclose a computer network for establishing treatment programs for said patients based on their respective patient health-related data and accumulated health-related data, as recited in claim 8. Seare et al does not overcome this deficiency and therefore does not teach or suggest receiving economic data relating to protocols used in these treatment programs.

In addition, Seare et al does not disclose or suggest aggregating population outcomes and generic standards of care with other data, as recited in claim 8. Joao is relied on in the Office Action to purportedly teach the recited clinical data comprising outcomes of the

treatment programs established by the claimed computer network. Applicants respectfully submit that, while Joao briefly mentions treatment monitoring and evaluation of treatment progress, Joao does not disclose generating clinical data comprising outcomes of treatment programs.

Seare et al uses historical medical provider billings to statistically establish utilization profiles. As indicated in Fig. 4 of Seare et al, a medical provider diagnosis indicated in the billing data can have one of three outcomes, that is, resolution, return to chronic disease state, or complication of the disease. If Seare et al can provide outcome information from medical provider billing data that may arguably teach clinical data as claimed, then such outcome data cannot be population outcome information as claimed.

Further, since the outcomes in Fig. 4 of Seare et al are only available from the raw billing data, they are not population outcomes as claimed. Seare et al uses CPT and other codes for reporting a medical service (see column 6, lines 7-9) and different tables to determine episodes of care to be included in the analysis and creation of a utilization profile for a medical provider. One table provides a numerical factor to adjust the frequency of a code based on age or gender in determining the provider's profile. This, however, only relates to that providers' medical services as evidenced in his billing records and not to outcomes of a population aggregated with the outcomes of medical services provided by that medical provider.

Since Seare et al does not overcome the deficiencies of Ballantyne et al and Joao, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 8-14 is respectfully requested.

C. Claims 15-21 and 23-25

Claims 15-21 and 23-25 are rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne and Joao in view of U.S. Patent No. 5,319,355 to Russek (hereinafter "Russek") and further in view of U.S. Published Application No. 2003/0055679, to Soll et al (hereinafter "Soll et al").

Applicants respectfully submit that Ballantyne does not teach accumulated health-related data as recited in independent claims 15 and 23 for the reasons stated above in connection with amended claim 1.

Applicants respectfully submit that neither Ballantyne nor Joao teaches updating said accumulated health-related data based on said patient health-related data, or identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions above in connection with amended claim 1 or 8.

In the Office Action, Soll et al is relied on to purportedly teach the following claim 15 recitations, among others:

> "*determining whether each respective patient is suitable for participation in a treatment program;*
> *wherein the determining step comprises the steps of*
> *obtaining agreement from a respective patient to participate in a treatment program; and*
> *receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient.*"

In Soll et al, the abstract is silent regarding determining if a patient is suitable for participation in a treatment program. The interview in paragraph [0058] of Soll et al and relied on in the Office Action refers to patient exit and revisit interviews to assess response to treatment and therefore relates to after any plan of care or treatment is administered. Nothing in Soll et al discloses or suggests receiving a plan of care as a result of an interview for use in the establishment of a treatment program. Further, for reasons stated above in connection with claims 1-7, Ballantyne does not disclose a establishing a treatment program for respective patients based on their respective patient health-related data and accumulated data relating to health-related conditions and treatments. In addition, neither Soll et al, Joao, nor Russek overcome the deficiencies of Ballantyne et al, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 15-20 is respectfully requested.

Claims 16-20 are not rendered obvious for reasons stated above in connection with claims 1-7.

Regarding claims 21 and 32, the referenced section of Joao is silent regarding a CPOC and MPOC as claimed. Column 4, lines 40-47 of Joao describe a database that can be accessed to provide treatment plans or programs, among other things. This section of Joao, however, is silent regarding developing a CPOP during a interview, or a MPOC via a primary care team member. The interview described in Soll et al is a patient exit and revisit interview and not an interview to develop a client plan of care.

Claim 23 recites determining whether each respective patient is suitable for participation in a treatment program and therefore is not rendered obvious for the reasons stated above in connection with claim 15.

In the Office Action, Joao is relied on to purportedly teach the following recitations of claim 23 which has been amended herein:

> "*coordinating said healthcare managers with at least one member of the primary care team to ensure the treatment programs are followed by respective said patients, tracking any changes to the MPOC and updating members of the primary care team regarding the changes; and*
>
> *updating said accumulated data in said database based on said patient health-related data provided by said healthcare managers, including revisions to the CPOCs and MPOCs for respective said patients and identifying improvements in standards of care and medical practices that can be made for different ones of the health-related conditions.*"

For reasons stated above in connection with claim 1, Joao does not teach updating said accumulated data or identifying improvements in standards of care and medical practices as claimed.

In view of the foregoing, independent claim 23 and its dependent claims 24 and 25 are not rendered obvious by the applied references herein. In addition, regarding claim 24, the referenced text at column 16, lines 38-65 of Joao lists patient data but is silent regarding documenting for storage patient-related communications during scheduled conferences and non-scheduled communications such as messages or an interview or conference communication.

D. Claim 22

Claim 22 is rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al, Joao, Russek, Soll et al in view of Official Notice. First, claim 22 depends from independent claim 15 which is not rendered obvious in view of the applied references for the reasons stated above. Second, Applicants respectfully submit that the Examiner has failed to cite a reference teaching excluding a patient from a treatment program based on the criteria that *the patient cannot communicate effectively* [emphasis added].

In the previous response, the Applicants traversed the rejection of claim 22 based on official notice and requested references for at least the disclosure of excluding a patient from a treatment program based on the criteria that the patient cannot communicate effectively.

In view of these remarks, if the Examiner does not intend to withdraw the rejection of the claim, Applicants request that the Examiner provide evidence in the next Office action regarding the requirements of the claim being known in the art or explain why no evidence is required. *See* MPEP § 2144.03.

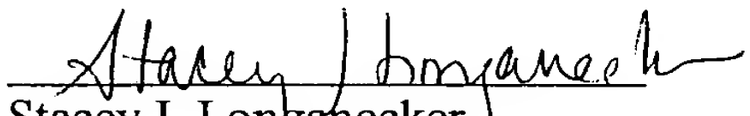
If the Examiner declines to provide evidence, and if the Examiner wishes to maintain a rejection based upon personal knowledge regarding the requirements of the claims being known in the art, Applicants request that such knowledge be stated as specifically as possible in an affidavit, in accordance with MPEP § 2144.03.

III. Conclusion

Accordingly, withdrawal of 35 U.S.C. § 103(a) rejections of the claims 1-25 is respectfully requested.

In view of the above, it is believed that the application is in condition for allowance, including claims 1-25, and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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